08/321179

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/321,179	10/11/94	CARNEY	W 40441CZJPWNP

EXAMINER	
SCHEINER, T	
ART UNIT	**PAPER NUMBER**
1806	4

18M2/1031

JOHN P. WHITE
COOPER AND DUNHAM
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

DATE MAILED: 10/31/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 7/10/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 18 are pending in the application.
   Of the above, claims 3 - 18 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1 and 2 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Applicant's election with traverse of Group I (claims 1 and 2) in Paper No. 2 is acknowledged. The traversal is on the ground(s) that "the p100 peptide and the monoclonal antibodies to neu are used in such related matters that searching both groups would not be a serious burden for the examiner . . . a search of the p100 literature would locate p100 monoclonal antibodies and vis versa." This has not been found persuasive because the inventions are classified in entirely different areas of the patent literature (Class 530, subclass 350 and Class 435, subclass 194 for p100; Class 530, subclasses 388.8 and 388.85, and Class 435, subclass 240.27 for monoclonal antibodies and hybridomas). Disclosure of p100 antibodies in documents classified in the places where p100 is classified would be purely fortuitous, and vice versa; searching all of the appropriate areas for both groups would place a serious burden on the examiner.

The requirement is still deemed to be proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities: the listing of related applications in the specification is incomplete. Only serial nos. 07/297,188, 07/182,501 and 06/871,102 are listed. There is at least one other application (07/412,668) which is not mentioned. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure.

According to the specification, the existence of p100 was noted when antibody raised against cell lysates recognized p185 in cell lysates, and also recognized a smaller related protein in cell culture supernatants and biological fluids. This is very little discussion of the physical and biological properties of p185 or p100 beyond this, therefore, the availability of at least one of the disclosed antibodies to the external domain of p185 must be assured to enable one of skill in the art to isolate and/or identify p100 without undue experimentation.

The specification lacks complete deposit information for the deposit of the hybridoma cell lines which secrete monoclonal antibodies OD3, NB-3 and TA-1. Because it does not appear that any of these antibodies are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the only disclosed means of isolating and/or identifying p100 requires the use of an antibody specific for the external domain of p185, a suitable deposit of any one of the disclosed hybridoma cell lines is required for patent purposes.

Applicants' referral to the deposit of OD3, NB-3 and TA-1 as HB 10204, HB 10205 and HB 10206 on page 9 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. Because the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Amendment of the

specification to recite the date of the deposit and the complete name and address of the depository is required.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "corresponds substantially to" is vague and indefinite The specification states that this term "provides for conservative additions, deletions and substitutions;" this is taken to mean conservative amino acid substitutions, but it still does not explain how much can be deleted from the protein without altering its identity, or how many amino acids can be added (p185 "corresponds substantially to" p100 by this definition).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Toni R. Scheiner whose telephone number is (703) 308-3983. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TRS
10/27/95

Toni R. Scheiner

TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1800